

Remarks/Arguments

Applicant has not added any claims in this reply, and has cancelled Claims 2, 3, 7, 8 and 13. Therefore, Claims 1, 4–6, 9–12 and 14–27 remain pending in this application.

Information Disclosure Statement

The Examiner declined to consider the information disclosure statement that was filed on 19 February 2004. Filed herewith is an information disclosure statement listing all of the references cited in the information disclosure statement of 19 February 2004. Except for References 123–131, all of the foreign and non-patent literature cited in the information disclosure statement filed herewith was cited in U.S. Patent Application 09/620,701 (filed 20 July 2000; now U.S. Patent 6,527,759), which is relied upon for an earlier effective filing date under 35 U.S.C. § 120. Therefore, copies of these references are not required under 37 C.F.R. § 1.98(d). Copies of References 123–131 are enclosed herewith. Applicants respectfully request that the Examiner consider all of the references cited in the information disclosure statement filed herewith.

Claim Rejections Under 35 U.S.C. § 112(¶2).

Claims 1–13 and 15–27 stand rejected under 35 U.S.C. § 112(¶2) as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Claims 2, 3, 7, 8 and 13 have been cancelled. Applicants have amended Claim 1 to remove the recitation of the “therapeutic composition comprising genetic material”. Claim 1 has also been amended to recite that the “ultrasound transducer generates a level of ultrasound energy that is sufficient to cause the ultrasound energy to penetrate tissue at the target site”, thereby clarifying for what the level of ultrasound energy should be sufficient. Claim 15 has been amended to clarify the antecedent basis for the “at least one support member”. Based on the foregoing, Applicants respectfully submit that Claims 1, 4–6, 9–12 and 14–27 particularly point out and distinctly claim the subject matter which Applicants regard as

their invention, and therefore satisfy the requirements of 35 U.S.C. § 112(¶2). Applicants respectfully request that the rejection of these claims be withdrawn.

Claim Rejections Under 35 U.S.C. § 112(¶1).

Claims 1–13 and 15–27 stand rejected under 35 U.S.C. § 112(¶1) as reciting subject matter that was not described in the specification in such a way as to enable an ordinarily skilled artisan to make and/or use the invention. Claims 2, 3, 7, 8 and 13 have been cancelled. Applicants have amended Claim 1 to clarify that the claimed method does not require that the nucleic acid be transfected into a cell. These amendments are fully supported by the originally-filed application disclosure; see for example paragraph [0393] of the published application. These amendments make clear that genetic material need not be properly incorporated into the genome and expressed.

The claimed method avoids many of the pitfalls and challenges of gene therapy as outlined by the Examiner. For example, the Examiner has taken the position that problems exist in achieving the appropriate level of expression within a cell or tissue. Applicants note that the claimed method does not require expression of the oligonucleotide. The Examiner has also taken the position that there is no single vector that has all the attributes of an ideal gene therapy vector. Even assuming, for the sake of argument, that this was true, Applicants note that vectors are not used in the claimed method since an oligonucleotide that is complementary to the DNA or the RNA of the target site is used. In the claimed method, delivery to the target site is facilitated by the recited catheter. Thus, the claimed method, as recited in amended Claim 1, avoids the problems as outlined by the Examiner, and does not require “gene therapy” as that term is used by the cited references. Based on the foregoing, Applicants respectfully submit that Claims 1, 4–6, 9–12 and 14–27 recite subject matter that is sufficiently described in the specification in such as way as to enable an ordinarily skilled artisan to make and use the invention, and therefore satisfy the requirements of 35 U.S.C. § 112(1). Applicants respectfully request that the rejection of these claims be withdrawn.

Claim Rejections Under 35 U.S.C. § 102(e).

Claim 14 stands rejected as being anticipated by U.S. Patent 6,680,301 ("Berg '301"). Independent Claim 14 has been amended to recite a therapeutic composition that comprises "a light activated drug **covalently bonded to** a nucleic acid" (emphasis added). This amendment is fully supported by the originally-filed application disclosure; see for example paragraph [0312] of the published application. The Examiner has pointed to no teaching of the therapeutic compound recited in amended Claim 14 in Berg '301. Applicants therefore respectfully submit that amended Claim 14 is allowable over Berg '301, and respectfully request that this rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 103(a).

Claim 14 strands rejected as being unpatentable over either U.S. Patent 5,876,989 ("Berg '989") or PCT Publication WO 96/07432 ("Berg '432"). Independent Claim 14 has been amended to recite a therapeutic composition that comprises "a light activated drug **covalently bonded to** a nucleic acid" (emphasis added). This amendment is fully supported by the originally-filed application disclosure; see for example paragraph [0312] of the published application. The Examiner has pointed to no teaching of the therapeutic compound recited in amended Claim 14 in either Berg '989 or Berg '432. Applicants therefore respectfully submit that amended Claim 14 is allowable over both Berg '989 and Berg '432, and respectfully request that this rejection be withdrawn.

Conclusion.

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although


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changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. If some issue remains that the Examiner feels can be addressed by an Examiner's Amendment, the Examiner is cordially invited to call the undersigned for authorization.

Respectfully submitted,

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